DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

   1. Determining the scope and contents of the prior art.
   2. Ascertaining the differences between the prior art and the claims at issue.
   3. Resolving the level of ordinary skill in the pertinent art.
   4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 13-15 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinicke (US Patent 4,626,244) in view of Somyk (US Patent 3,571,815).

Reinicke discloses an implantable drug pump system (abstract; figure 1), comprising: a catheter (120) for delivering infusate from the system (column 7, lines 50-65); an implantable infusion device (10), the implantable infusion device comprising a reservoir (18), to hold infusate and a pump mechanism (20), for pumping the infusate; a bolus port member (40) adapted to receive a bolus injection from a needle (column 5, lines 18-33) in an interior space (62) of the bolus port member; a member for implantation within a living body, comprising a first portion (10) to receive and hold the implantable infusion device, a second portion (22) to receive and hold the bolus port member (40), the second portion adapted to receive or couple to a proximal end of the catheter (120), the second portion further adapted to provide a continuous fluid flow path (32) between an outlet (38) of the implantable infusion device, the interior space of the bolus port member (62, 72, 74), and the proximal end of the catheter (120), and the second portion comprises an inner groove (recess 34) as part of the continuous flow path.

Reinicke fails to teach that the implantable member is an elastomer with a suturable skirt.

Somyk teachs an elastomer member for implantation within a living body (figure 1), the elastomer member to receive and hold the implantable infusion device (figure 1, 11); and an enlarged skirt (12), the skirt includes a reinforcement material (column 2, line 13) which extends substantially around a perimeter of the elastomer member (figure 3, 12), adapted to receive and retain a suture (column 2, lines 25- 30) to secure the elastomer member at an implantation site (column 4, line 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the drug pump device of Reinicke, which is intended to be implanted into the body of a patient (and covered by an elastomer, 98), with the elastomer skirt member of Somyk since the skirt would allow for implantation into tissue (Somyk: column 3, lines 54-56; column 4, lines 1-5).

4. Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinicke (US Patent 4,626,244) in view of Somyk (US Patent 3,571,815).

Reinicke discloses an implantable drug pump system (abstract, figure 1), comprising: a catheter (120) for delivering infusate from the system (column 7, lines 50-65); an implantable infusion device (10), the implantable infusion device comprising a reservoir (18) to hold infusate and a pump mechanism (20) for pumping the infusate; a bolus port member (40) for receiving a bolus injection from a needle (column 5, lines 18-33), the bolus port member comprising a septum (60), a needle stop structure (64), and an interior space (62) disposed between the septum and the needle stop structure; a member for implantation within a living body, comprising a first annular ring (flat circular housing, 10) adapted to receive and hold the implantable infusion device (formed by 12 and 14), a second annular ring (see figure 1, indicated by 64) adapted to receive and hold the bolus port member (40), the second portion (22) further adapted to receive or couple (via 34) to a proximal end of the catheter (120), the second portion (22) further adapted to provide a continuous fluid flow path (32) between an outlet (38) of the implantable infusion device, the interior space of the bolus port member (62, 72, 74), and the proximal end of the catheter (120) and the second portion comprises an inner groove (recess 34) as part of the continuous flow path.

Reinicke fails to teach that the implantable member is an elastomer with a suturable skirt.

Somyk teachs an elastomer member for implantation within a living body (figure 1), the elastomer member to receive and hold the implantable infusion device (figure 1, 11); and an enlarged skirt (12), the skirt includes a reinforcement material (column 2, line 13) which extends substantially around a perimeter of the elastomer member (figure 3, 12), adapted to receive and retain a suture (column 2, lines 25- 30) to secure the elastomer member at an implantation site (column 4, line 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the drug pump device of Reinicke, which is intended to be implanted into the body of a patient (and covered by an elastomer, 98), with the elastomer skirt member of Somyk since the skirt would allow for implantation into tissue (Somyk: column 3, lines 54-56; column 4, lines 1-5).

Response to Arguments

5. Applicant's arguments with respect to claims 13-15 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner has withdrawn the objections to both the drawings and specification in view of the corrections provided by the Applicant.

The Applicant has amended claim 13 to include limitations of originally presented dependent claims 16, 17, 18, and 25, as well as including new limitations of the actual infusion device and bolus port member. Applicant has also amended claims 14-15 to include the implantable drug pump system over the elastomer member previously claimed. Applicant has cancelled claims 16-36 and added new claims 37-41.

Applicant’s amendments necessitated the new grounds of rejection however certain arguments will be address below.

The Applicant argues that Somyk does not contain an infusion device, and is merely a suture ring.

The Examiner agrees, however as claim 13 was originally presented, the Applicant was only claiming the suturable housing for the infusion device, and not the infusion device itself. Therefore, this argument is moot.

The Applicant argues that Srisathapat does not contain a continuous fluid path through the second portion of the elastomer member.

The examiner disagrees. The drug infusion pump of Srisathapat did have two portions of the housing member, and there was a continuous fluid path through the second portion. The housing of Srisathapat was not disclosed as an elastomer, and was therefore rejected in combination with Somyk, which had an elastomer member for implantation, which could receive the infusion pump of Srisathapat.

The applicant argues that the elastomer housing of McIntyre does not have a second portion to hold the bolus port member.

The examiner agrees. However, the rejection was based on the second portion of Srisathapat in combination of the elastomer material of McIntyre. The rejection was not suggesting that McIntyre taught a second portion to hold the bolus port member. Therefore, the argument is moot.

The applicant argues that Yannas does not teach or suggest any structure for implantable infusion devices.

The examiner disagrees. Yannas teaches a biocompatable elastomer, which could be used as a housing for implantable infusion devices. This reference was used as an example of an elastomer.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARTI BHATIA whose telephone number is (571)270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Joseph Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Joseph S. Del Sole/
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